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| 10/726,463 | 12/03/2003 | Richard Hayes | AQMED.0101 | 5879 |

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| EXAMINER | |
|---|---|
| MACNEILL, ELIZABETH | |
| **ART UNIT** | **PAPER NUMBER** |
| 3767 | |

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/726,463 | HAYES ET AL. | |
| | Examiner | Art Unit | |
| | Elizabeth R. MacNeill | 3767 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *31 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

This action is in response to applicant's arguments submitted 31 October 2006.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 6-7, 9-10, 13, 15-21,23, 25-28, 30-31, 34-38, 40, 42, 46-50, 52, 55, 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Bene et al. (PN 5,698,090).

Regarding claims 1,25, 42 Bene et al. discloses a first pump (See Figure 1 (12)) that is configurable to pump a first metered (See Column 3 Lines 57-67, Column 4 Lines 1-13, 59-67, Column 5 Lines 1-8) amount of a first fluid through a first delivery line (See Figure 1 (11)) to a catheter (See Figure 1 (Between (8) and (9))); a second (See Figure 1 (22)) pump that is configurable to pump a second metered (See Column 3 Lines 57-67, Column 4 Lines 1-67, Column 5 Lines 1-17) amount of a second fluid through a second delivery line (See Figure 1 (21)), separate from said first delivery line, to said catheter (See Figure 1 (Between (8) and (9))); a processor (See Figure 1 (25)), connected to control said first and said second pumps such that said second metered amount has a definable relationship to said first metered amount (See Column 3 Lines 57-67, Column 4 Lines 1-13, 59-67, Column 5 Lines 1-17); wherein the lumen of said first delivery line and the lumen of said second delivery line remain separate up to a

connection point (See Figure 1 (8)) of said first and second delivery lines to said catheter.

Regarding claim 2 Bene et al. discloses the first fluid is an oxygen-carrying solution (See Figure 1 (10), Column 3 Lines 34-39).

Regarding claim 3 Bene et al. discloses the first fluid is blood (See Figure 1 (10), Column 3 Lines 34-39).

Regarding claim 4 Bene et al. discloses first fluid comprises blood from the patient (See Figure 1 (6), (7)).

Regarding claim 6 Bene et al. discloses a plurality (See Figure 1 (6), (19)) of additional pumps pumping respective (See Column 3 Lines 34-44, Column 4 Lines 14- 48) fluids under the control of said processor (See Figure 1 (25)).

Regarding claims 7, 55 Bene et al. discloses first pump (See Figure 1 (12)) is further configurable to combine a third metered amount of a third fluid with the first fluid and to pump both the first and the third fluids into said first delivery line (See Column 3 Lines 34-67, Column 4 Lines 1-67, Column 5 Lines 1-8).

Regarding claim 9 Bene et al. discloses said processor (See Figure 1 (25)) receives feedback from monitors (See Figure 1 (23), (24), Column 3 Lines 57-67, Column 4 Lines 1-13) and can automatically alter operational parameters to meet predefined objectives.

Regarding claims 10, 57 Bene et al. discloses an operator can alter the definable relationship between said first metered amounts and said second metered amount (See Column 6 Lines 33-67).

Regarding claim 13 Bene et al. discloses a monitor (See Figure 1 (25)) to detect one or more conditions, the conditions including the rate of flow (See Column 3 Lines 24-67, Column 4 Lines 1-67, Column 5 Lines 1-8), the temperature, the pressure, and the concentration of a fluid within said pumping system.

Regarding claims 15, 34, 46 Bene et al. discloses said processor (See Figure 1 (25)) is connected to control the activity of a portion (See Column 3 Lines 24-67, Column 4 Lines 1-67, Column 5 Lines 1-8) of said clinical fluid pumping system.

Regarding claims 16, 35, 47 Bene et al. discloses said processor is connected to control the operation of a valve (See Figure 1 (15), (16)).

Regarding claims 17, 36, 48 Bene et al. discloses said processor is connected to control (See Column 3 Lines 57-67, Column 4 Lines 1-13, 59-67, Column 5 Lines 1-8) the speed of said first pump.

Regarding claims 18, 37, 49 Bene et al. discloses said processor (See Figure 1 (25)) is connected to receive inputs from a monitor (See Figure 1 (23), (24)) and to send signals to control a portion of said clinical fluid pumping system.

Regarding claims 19, 38, 50 Bene et al. discloses a display and control panel (See Figure 1 (25)) connected to provide information regarding the operation of said pumping system to a user and to accept input from the user (See Column 4 Lines 59-63, Column 6 Lines 33-67).

Regarding claim 20 Bene et al. discloses said first (See Figure 1 (11)) delivery line and said second delivery (See Figure 1 (21))line are separate lumen within a single tubing (See Figure 1 (8)).

Regarding claims 21, 40 Bene et al. discloses said first delivery line (See Figure 1 (11)) and said second (See Figure 1 (21)) delivery line are separate pieces of tubing.

Regarding claims 23, 52 Bene et al. discloses said catheter (See Figure 1 (9)) is directly inserted into a circulatory vessel serving a target organ and has a single lumen.

Regarding claim 26 Bene et al. discloses said pumping means consists of a first (See Figure 1 (12)) pump.

Regarding claim 27 Bene et al. discloses said pumping means comprises a first (See Figure 1 (12)) pump and a second (See Figure 2 (22)) pump.

Regarding claim 28 Bene et al. discloses the co-mingling of the first fluid and the second fluid is delayed (See Figure 1 (11), (21)) to prevent degradation of the second fluid.

Regarding claim 30 Bene et al. discloses means (See Figure 1 (25)) to control (See Column 3 Lines 24-67, Column 4 Lines 1-67, Column 5 Lines 1-8) the fluid flow rate.

Regarding claim 31 Bene et al. discloses a means to control (See Column 3 Lines 24-67, Column 4 Lines i-67, Column 5 Lines 1-8) the known relationship between the first and the second fluids.

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 5, 39, 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bene et al. (PN 5,698,090) in view of Gillies et al. (PN 6,272,370). Bene et al. discloses the invention as recited in claims 1,25, 42 however, fails to disclose said pumping step pumps adenosine.

Gillies et al. teaches that it is conventional in the art for said pumping step to pump adenosine (See Column 23 Lines 51-60).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have pumped adenosine as taught by Gillies et al. in the Bene et al. device since it would improve catheter-based administration of medicine.

3. Claims 8, 12, 29, 32, 43-44, 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bene et al. (PN 5,698,090)in view of Hogard et al. (PN 6,284,131). Bene et al. discloses the invention as recited in claims 1, 25, 42 however, fails to disclose the fluids are delivered at a controlled temperature and pressure; comprising a temperature controller, configurable to provide heating or cooling to fluids in at least one of said first delivery tube and said second delivery line without contaminating the fluids; passing at least one of the fluids through a heat exchanger, whereby the at least one of the fluids is brought to a desired temperature prior to delivery to said catheter.

Hogard et al. teaches that it is conventional in the art to utilize the fluids are delivered at a controlled temperature and pressure (See Column 2 Lines 1-15, Column 4 Lines 25-36); comprising a temperature controller, configurable to provide heating or cooling to fluids in at least one of said first delivery tube and said second delivery line without contaminating the fluids (See Column 2 Lines 1-15, Column 4 Lines 25-36); passing at

least one of the fluids through a heat exchanger (See Figure 1A (16)), whereby the at least one of the fluids is brought to a desired temperature prior to delivery to said catheter (See Figure 1A (16), Column 2 Lines 1-15, Column 4 Lines 25-36).
It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the temperature and pressure control and heat exchanger taught by Hogard et al. in the in the Bene et al. device since it would improve the health of the dialysate recipient.

4. Claims 11, 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bene et al. (PN 5,698,090).

Bene et al. discloses the invention as recited in claims 1,42 above, however, fails to disclose the second delivery line contains a one-way check valve to prevent retrograde flow. Bene et al. teaches that it is conventional in the art to utilize the first delivery line contains a three-way check valve (See Figure 1 (15)) to prevent retrograde flow.
It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the check valve taught by Bene et al. in the first delivery line in the second delivery line since it would prevent retrograde flow in the second delivery line.

5. Claims 14, 33, 45 are rejected under 35 U.S.C. 103(a)as being unpatentable over Bene et al. (PN 5,698,090) in view of Collins et al. (PN 6,303, 036).
Bene et al. discloses the invention as recited in claims 1, 25, 42 however, fails disclose a monitor to detect the temperature or blood pressure of a patient coupled to said pumping system.

Collins et al. teaches that it is conventional in the art to utilize a monitor to detect the temperature or blood pressure of a patient coupled to said pumping system (See Column 5 Lines 34-37).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized detecting the blood pressure of a patient since it would improve the effectiveness of the dialysis machine.

6. Claims 22, 41, 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bene et al. (PN 5,698,090).

Bene et al. discloses the second fluid is co-mingled with the first fluid a short distance from a target organ (See Figure 1 (9)).

Bene et al. does not disclose expressly the two fluids are co-mingled no further than twelve inches from a target organ. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to limit the co-mingling distance to twelve inches because Applicant has disclosed it is well known in the art that the reactivity of adenosine with blood dictates a reduced delivery distance to the patient. Therefore, it would have been an obvious matter of design choice to modify Bene et al. to obtain the invention as specified in claims 22, 41, 54.

7. Claims 24, 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bene et al. (PN 5,698,090).

Regarding claims 24, 53 Bene et al. discloses the invention as recited in claims 1,42 above and further discloses said catheter is inserted into a circulatory vessel (See

Figure 1 (9)) remote from a target organ and maneuvered to the target organ, said catheter having a single lumen (See Figure 1 (9)).

Bene et al. discloses the claimed invention except for the multiple lumens. It would have been obvious to one having ordinary skill in the art at the time the invention was made to increase the number of lumen, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis paper Co. v. Bemis Co., 193 USPQ 8, and this duplication would not produce unexpected results.

***Response to Arguments***

8. Applicant's arguments filed 31 October 2006 have been fully considered but they are not persuasive.

9. Regarding claims 1,25, and 42, the applicant has argued that Bene does not teach a connection point (page 4). The definitions the applicant has submitted definitions of "connection" and "point" which the examiner does not believe are the most applicable to the present application. The definition of point submitted by the applicant is "something though of as having a definite position in space, but no size or shape." This is an abstract definition of the geometrical meaning of "point." The examiner submits the definition "a specific place or location" which is believed to better represent the contextual meaning of point in the claims. The applicant's own invention would not meet the proposed definition of having no size or shape, since the "connection point" shown in the figures clearly has both size and shape (believed to be at 382). The device of Bene et al shows the two fluid lines meeting at the bubble trap (8) which has a specific

place and location. The slowing of the fluid passing through the bubble trap is irrelevant because it is not recited in the claims.

Applicant further argues Bene does not teach a catheter. This is not labeled in the Figures of Bene but clearly shown Fig 1. Applicant has argued that the fluid lines deliver to a bubble trap, not a catheter. The bubble trap is believed to be an extension of the fluid delivery lines and the mixed fluid is delivered to the catheter as recited in the claims.

10. Regarding the rejection of claims 5,39, and 51 of Bene in view of Gillies. Applicant argues that Gillies teaches only the delivery of adenosine, not the delivery of adenosine mixed with blood. In response to applicant's argument that the adenosine is not mixed with blood, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). As Gillies teaches the delivery of adenosine via a catheter into the patient, it would have been obvious to include adenosine in the delivery mixture sent to the patient via a catheter.

11. Regarding the rejection of claims 8,12,29,32, 43,44, and 56 of Bene in view of Hogan and the rejection of claims 14,33, and 45 of Bene in view of Collins, applicant has argued only that Bene fails to teach the limitations of independent claims 1,25, and 42. This argument has been answered above.

12. Regarding the rejection of claims 11 and 58 over Bene, applicant has argued that the three-way check valve (15) does not prevent retrograde flow. Bene states that "the blocking means...are for allowing the substitution/dialysis liquid to flow out into the circuit..." which examiner takes to mean prevents the liquid from flowing in the opposite direction (i.e. preventing retrograde flow). It would have been obvious to prevent retrograde flow in the second delivery line as well. The function of the bubble trap is not to prevent retrograde flow, as asserted by the applicant, but rather to prevent air bubbles from being delivered to the patient.

13. Regarding the rejection of claims 22,41, and 54 over Bene, applicant has argued that the fact that commingling occurs less than 12 inches from the patient is a unique advantage of the present invention which is not disclosed by Bene. Applicant has shown that it is well known in the art to use a distance of 12 inches or less in disclosing that "the maximum co-mingling distance is twelve inches when adenosine is to be mixed because its reactivity is such that it should not be mixed with blood until shortly before reaching the target organ. Given that the general reactivity of adenosine with blood and the approximate flow rate of an MPS system are *known by those skilled in the art,* the disclose that the co-mingling distance is limited to twelve inches *would serve to disclose to a person skilled in the art.*" (page 10, emphasis added).

14. Regarding the rejection of claims 24 and 53 over Bene, applicant has argued that because the multiple lumen catheter reduces commingling it produces a new and unexpected result. As discussed above, the reduced co-mingling is not a new and excepted result, but rather a result well known in the art. The use of a dual-lumen

catheter would have been a matter of obvious design choice to one of ordinary skill in the art at the time the invention was made.

***Conclusion***

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

12/8/06

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